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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/615,624	07/13/2000	Peter C. Brooks	13761-734	3563

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EXAMINER	
NICKOL, GARY B	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/615,624	BROOKS ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6 and 8-104* is/are pending in the application.

4a) Of the above claim(s) *18-21 and 25-104* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,8-17 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Re: Brooks *et al.*

Date of priority: 07-13-1999

Response to Amendment

The Amendment filed 04/26/04 in response to the Office Action of 12/23/2003 is acknowledged and has been entered.

Claims 1, 5-6, and 8-104 are pending.

Claims 18-21, and 25-104 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 1, 5-6, 8-17, 22-24 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 15-16 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure for the reasons of record. Applicants argue (Response filed 04/26/04, page 13) that a recent Federal Circuit decision (*Noelle v. Lederman, 355 F.3d 1343 (Fed.Cir.2004)*) has summarized the written description requirements with respect to antibodies wherein as long as an applicant has disclosed a fully characterized antigen, either by its structure, formula, chemical name, or

physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that describe antigen. This argument has been considered but is not found persuasive because the facts of that decision do not directly parallel the current rejection. Nowhere does this decision revoke the requirements of a monoclonal antibody deposit when said specific antibody is claimed by name. Applicants are reminded that the current rejection is a deposit rejection for the FM155 monoclonal antibody based on a 112 1st paragraph, enablement. Even though, applicant's have amended the claims to indicate what antigen the antibody binds too, it remains unclear if a cell line which produces an antibody having the *exact* structural and chemical identity of monoclonal antibodies selected from the group consisting of **FM155,** are known and publicly available, or can be reproducibly isolated without undue experimentation. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 1, 5-6, 8-17, 22-24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over MELVIN *et al.* (WO 97/00449, January 1997) in combination with the teachings of Newton *et al.* (Int'l. Jnl. Oncol., Vol. 6, pages 1063-1070, 1995) for the reasons of record.

Applicants argue (page 16) that amended claim 1 is directed to an antagonist that modifies interaction between MMP-9 and β1-containing integrins. Applicants argue that neither reference suggests binding of MMPs and integrins, much less antigens modifying such binding. For example, applicants argue that Melvin does not teach or suggest an antagonist affecting binding of MMP-9 to a β1-containing integrin. Applicants go on to characterize the teachings of Melvin in that Melvin generally describes preventing activation of MMPs by blocking access of

substrates or cofactors to catalytic sites on the enzyme. Applicants additionally argue that Melvin generally states that MMPs are capable of degrading extracellular matrix or interstitial connective tissue. Applicants also argue that none of the proteins that make up the extracellular matrix includes integrins. These arguments have been carefully considered but are not found persuasive for the reasons of record. Despite the amendment to claim 1, Melvin successfully suggests the use of therapeutic antagonists for the purpose of treating cancer wherein said antagonist interacts with at least one amino acid sequence within MMP-9 and or "modifies protein-protein interactions, wherein the protein-protein interactions comprise interactions between at least one amino acid sequence within MMP-9. The fact that Melvin does not teach nor suggest that the antagonist also modifies the protein-protein interactions with at least one amino acid within a β1-containing integrin was previously pointed out in the original rejection and is further not relevant to an otherwise obvious-type rejection under 35 USC 103.

Applicants further argue that the teachings of Melvin disclose a genus, while the presently claimed antigen that modifies binding of MMP-9 and β1-containing integrin is only "one type of many possible antigen". Thus, it appears that applicants are arguing that they have claimed a species (in claim 1) wherein "a prior genus does not render a later species claim unpatentable under 103 if it is demonstrated that the particular species claimed has unique and unexpected advantages or properties that distinguish it from other species within the prior genus. Applicants also separately characterize the teachings of Newton (page 18) as failing to teach binding of integrins to MMPs. Applicants reiterate (page 17) that it was not known or expected in the art that proteolytic enzymes, such as MMPs, may bind directly to integrins (emphasis added).

These arguments have been carefully considered but are not found persuasive. Applicants have not demonstrated that the claims define a particular species because, as set forth previously, the claims encompasses a genus of antagonists. Also, the claims do not require that MMP9 bind directly to integrins. The claims are drawn to the products *per se;* or those that modify protein-protein interactions. Any mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Thus, although the prior art does not specifically anticipate the claimed functional interactions, it is the combination of the references that would inherently lead to the modification of the protein-protein interactions. Further, the mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 1, 5-6, 8-14, 16-17, and 22-24 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicants argue that the amendment to the Claim 1 properly omits unnecessary nuances and focuses on the key aspects of the present invention. Applicants argue that a specification need not "describe the exact details for preparing every species within the genus described". Applicants argue that the genus of antagonists are adequately described via their common functional feature- the ability to modify an interaction between MMP-9 and β1-containing integrins. This argument has been

considered but is not found persuasive. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court has since clarified that this standard also applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., __F.3d ,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). Hence, the instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus, and the specification fails to provide a representative number of antagonists that encompass the stated functional activity. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of one species of antagonist remains insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

July 2, 2004

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER